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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/378,759	08/23/1999	GARY M. FOX	06843.0027-0	9481

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EXAMINER
BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
1646	21

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/378,759	Fox et al.
Examiner	**Art Unit**
Michael Brannock	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Feb 19, 2003* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☒ they raise the issue of new matter (see NOTE below);

(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *see Attachment to Advisory Action*

3. ☒ Applicant's reply has overcome the following rejection(s):
see Attachment to Advisory Action.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see Attachment to Advisory Action

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: *38-56*

Claim(s) withdrawn from consideration: *28, 29, 31, 36, and 37*

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. ☐ Other:

Attachment to Advisory Action

1. The amendment filed 2/19/03 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: raises new issues with regard to written description and new matter.

Claim 47 is proposed to be amended to include the limitation that the antibody be raised against at least a portion of a polypeptide comprising SEQ ID NO: 11, wherein the portion is not identical to any portion of CeK5. This proposed amendment would raise new issues regarding the written description requirement of 35 U.S.C. 112, first paragraph. Upon reading the specification, the skilled artisan would not recognize that Applicant was in possession of such a genus of claimed antibodies. There is no statement in the specification that antibodies should be raised in this way, and nor does there appear to be any motivation or suggestion that this should be done.

The proposed amendment would also be objected to as introducing new matter into the specification. As set forth above, there does not appear to be any support for the proposed limitation. Applicant argues at page 2 of Paper 20, that support for the amendment can be found at, e.g., page 4 lines 20-21. Applicant asserts that the specification presents a positive recitation of Cek5, and thus, the negative recitation of Cek5 in the claims is supported, MPEP 2173.05(i). This argument has been fully considered but not deemed persuasive. The specification merely indicates that Cek5 is the chicken homolog of Hek5. The skilled artisan would not interpret this statement as being a positive counterpart to the claimed antibody, e.g. the specification does not

teach that antibodies should be raised to at least a portion of a polypeptide comprising SEQ ID NO: 11, wherein the portion is identical to any portion of CeK5 - such a positive recitation might be viewed as Applicant suggests, however there appears to be no such positive statement.

Outstanding Issues:

2. Applicant is notified that the Drawings submitted 2/19/03 are accepted.

3. Claims 43, 46, 51 and 56 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims require a pharmaceutical composition yet the specification does provide sufficient guidance as to what the antibody is therapeutically effective for; and neither can such a use be reasonably inferred from the prior art, as set forth previously.

Applicant argues that the recitation of "pharmaceutical composition" is in the preamble and therefor carries no patentable weight, MPEP 2111.02. This argument has been fully considered but not deemed persuasive. The claim requires a pharmaceutical composition comprising the antibody. The intended use is as a pharmaceutical composition. As set forth previously, the term "pharmaceutical composition" implicitly requires that the composition can be used in a therapy or treatment. The fact that it may be used for something else, as Applicant suggests, is beside the point.

4. The rejection of claims 47 and 52 rejected under 35 U.S.C. 102(b) as being anticipated by Pasquale EB, Cell Regulation 2(7)523-534, 1991, as set forth in item 10 of Paper 15, 4/4/02, of Paper 12 would be withdrawn had Applicant's amendments been entered.

5. The rejection of claims 38-42, 44, 45, 48-50, 53-55 under 35 U.S.C. 103(a) as being unpatentable over Pasquale EB, Cell Regulation 2(7)523-534, 1991, as applied to claims 47 and 52 above, in view of U.S. Patent No: 4816567, would be withdrawn had Applicant's amendments been entered.

6. Claims 42, 44, 45, 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwase et al., Biochem. Biophys. Res. Comm. 194(2)698-705, 1993 in view of U.S. Patent No: 4816567, as set forth in item 10 of Paper 19.

Applicant argues that Iwase et al. never assert that the H1 polypeptide is upregulated and that the mRNA encoding H1 was all that was asserted to be upregulated. Applicant is technically correct, however, one of ordinary skill in the art would read Iwase et al. with the presumption that the polypeptide was also, more likely than not, up regulated as well, and that the primary focus of Iwase et al. is the potential role of the encoded protein and not the mRNA, e.g. in the Introduction (pg 698) Iwase et al. discuss the role of protein kinases in gastric cancers - thus refering to the protein and not to mRNA. The first sentence of the summary indicates that the focus of this plan of research is to find protein tyrosine kinases, identification of mRNAs

encoding the kinases being a first step in this process. Regardless, it is readily apparent that one of ordinary skill in the art would be motivated to make antibodies to the protein sequence disclosed by Iwase et al. to study the role of H1 in the development of gastric cancers, e.g. in the potential for diagnosis and/or treatment, as set forth previously.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

April 2, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600